



www.biistate.net



BISNIS Search for Partners – Leads from the BioIndustry Initiative

INDUSTRY:

**MEDICAL
EQUIPMENT AND
PRODUCTS,
PHARMACEUTICALS,
HEALTH CARE
SERVICES**

COMPANY /

INSTITUTE:

State Research Institute
of Highly Pure
Biopreparations, St.
Petersburg
www.hpb-spb.com

COUNTRY: Russian
Federation

Contact the BioIndustry Initiative:

Maria Douglass
Deputy Program Director,
Accelerated Drug & Vaccine
Development
BioIndustry Initiative
www.biistate.net
EurasiaBio2006@biistate.net
tel. 1.703.298.1276

NOVEL SYNTHETIC PEPTIDE IMMUNOMODULATORS AND CGMP MANUFACTURE OF SYNTHETIC PEPTIDE DRUGS

ABSTRACT: Highly Pure is developing novel non-toxic synthetic peptide immunomodulators on the basis of chemically modified HDPs (host defense peptides). HDPs are endogenous low-molecular mass molecules exhibiting varied activity against bacteria, fungi and viruses. HDPs are an integral component the cocktail of antimicrobial factors that operate synergistically *in vivo* against infection. Highly Pure has over 10 years of experience in this field and more than 80 analogs of HDP's have been chemically synthesized and their antimicrobial and hemolytic activities assessed. Based upon the data generated, these synthetic peptides are very promising for development as immunomodulating therapeutics. Modulation of the immune response is an emerging therapeutic approach that has the potential to impact a broad range of indications: infection, cancer, inflammatory disease, emergency situations following natural disasters and bioterrorism. The growing need for novel therapies in infectious, cardiovascular, oncologic and metabolic diseases, central nervous system disorders and others, calls for the development of new peptide therapies. After over two decades of specializing on small-scale peptide synthesis for R&D purposes, Highly Pure is now in a position to offer high-quality peptide products for preclinical and clinical trials, and is seeking partnering in its emerging cGMP contract peptide production business. The peptide therapeutic market is currently estimated at US\$1billion and growing at an average annual rate of 40% (*Business Communications Company*, 2005). According to F&S, there are more than 40 peptides marketed worldwide, around 270 peptides in clinical phase testing, and about 400 in advanced preclinical phases. Highly Pure has 25 years of experience in peptide synthesis, a team of skilled experts, and flexible technology of solid phase synthesis and production. Peptides are being synthesized by both Boc- and Fmoc-technologies, purified by preparative reverse-phase HPLC, characterized by amino acid analysis, MS and analytical HPLC data. Upon request Highly Pure can also determine peptide, water and counter ions contents, amino acid sequence, as well as NMR investigations. After specializing on

small-scale peptide synthesis for R&D purposes, Highly Pure has now adopted and used innovative approaches to constructing peptide libraries, chemical ligation methods, and the synthesis of peptidomimetics. Four years ago Highly Pure built production facilities for synthesis of peptide substances in bulk quantities. Highly Pure's focus is on providing not only high quality compounds, but also low manufacturing cost and short time of delivery.

TYPE OF PARTNERSHIP OFFERED: Highly Pure seeks a strategic partnership for co-development of its novel synthetic peptide immunomodulators, investment in facilities upgrades for cGMP manufacture of synthetic peptide drugs on a contract basis and access to international market channels.

COMPANY / INSTITUTE ROLE: Highly Pure is developing novel, non-toxic synthetic peptide immunomodulators on the basis of chemically modified HDPs (host defense peptides). In addition, Highly Pure produces peptides according to Russian GMP standards and is upgrading processes to meet international cGMP. Highly Pure's goal is to provide high-quality (cGMP) peptide products for preclinical and clinical trials. Additionally, Highly Pure plans to offer certified and validated analytical procedures for technical support to biological and medical research.

CURRENT STATE OF DEVELOPMENT: preclinical

OTHER INFORMATION

Institute representatives will be attending BIO2006 (Chicago, April 9 – 12, 2006) and welcome the opportunity to meet with interested parties during the event. For more information:

<http://www.biistate.net/docs/bio2006.php> or email: EurasiaBio2006@biistate.net

ABOUT THE INSTITUTE:

Highly Pure specializes in novel therapeutics and diagnostics based on immunological principles: particularly, the production of cytokines and peptides of medical interest; novel drug delivery systems; new adsorption materials for purification of proteins and extracorporeal therapy. Highly Pure's staff includes 300 highly skilled biologists, physicists, chemists, physicians, mathematicians and engineers. The Institute has pilot production facilities that are certified by the Russian Ministry of Health and Social Development to manufacture drugs based on its proprietary gene-engineered proteins and synthetic peptides. This facility is currently being upgraded to comply with international cGMP. Highly Pure manufactures the following biopharmaceuticals for domestic and near-abroad markets:

- Betaleukin® – the world's first drug based on the recombinant human interleukin-1 β for oncology, infectious diseases and for protection from radiation;
- Epocrin® - based on recombinant human erythropoietin, for therapy of oncologic and infectious diseases;
- Interalf® – based on recombinant human interferon α -2a, for therapy of oncologic and infectious diseases
- Allokin-alpha® – synthetic peptide-based drug for the treatment of genital Herpes and other viral diseases;

- Glutoxim® - synthetic peptide-based immunostimulatory drug for the therapy of oncologic and infectious diseases;
- Bestim® - immunostimulatory peptide-based drug for therapy of infectious diseases and for protection from radiation.
- Vitaflor™ – a complex bacterial preparation for prophylaxis and treatment of dysbacteriosis
- Chitoskin™ – biodestructable wound healing bandages based on chitosan and collagen for the therapy of wounds, burns, ulcers, and skin inflammations

MAJOR CUSTOMERS / INTERNATIONAL EXPERIENCE:

Biopharmaceuticals manufactured by Highly Pure for domestic and near-abroad markets are sold through the major pharmaceutical products distributors on those territories. Researchers at the Highly Pure are collaborating with scientists at top universities in the U.S., such as the Yale University School of Medicine, the University of North Carolina, and the University of California at Berkeley, the National Institute of Health, and the Massachusetts General Hospital, among others. Highly Pure has extensive experience with international grants from organizations such as the International Science & Technology Center (www.istc.ru) and the US Civilian Research & Development Foundation (www.crdf.org).

PARTNERSHIP OPPORTUNITIES FROM BII. The BioIndustry Initiative (BII) is a nonproliferation program of the US Department of State's Bureau of International Security and Nonproliferation - Office of Cooperative Threat Reduction (ISN-CTR). BII's mission is to counter the threat of bioterrorism through targeted transformation of former Soviet biological weapons research and production capacities.

DISCLAIMER. The leads are sourced by the BioIndustry Initiative through our partner organizations in Russia and other Eurasian countries. Leads are provided solely as an information resource and do not represent an endorsement by BII or the U.S. Departments of State and Commerce. Verification of the leads is the responsibility of the reader. Assistance conducting due diligence and negotiations with Eurasian companies/institutes may be provided in some cases. Contact BII for more details: bii@biistate.net.